DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 17, 2014

Topcon Corporation
% Ms. Maureen O'Connell
O'Connell Regulatory Consultants
5 Timber Lane
North Reading, MA 01864

Re: K141481
Trade/Device Name: TRC-NW400 Non-Mydriatic Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: August 12, 2014
Received: August 13, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141481

Device Name
TRC-NW400 Non-Mydriatic Retinal Camera

Indications for Use *(Describe)*

The TRC-NW400 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without use of a mydriatic.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Non-Mydriatic Retinal Camera TRC-NW400

510(k) Owner
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Date Prepared: May 29, 2014

Name of Device and Name/Address of Sponsor
Non-Mydriatic Retinal Camera TRC-NW400

Common or Usual Name
Retinal Camera

Classification Name
Camera, Ophthalmic, AC-Powered
21 C.F.R. 886.1120
Product Code: HKI

Predicate Devices
Non-Mydriatic Retinal Camera TRC-NW300 (K123460)

Indications for Use
The TRC-NW400 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without use of a mydriatic.

Technological Characteristics
The Topcon TRC-NW400 is a fundus camera designed to observe, photograph and record the fundus oculi of a patient's eye with or without the use of a mydriatic. The TRC-NW400

does not come into contact with the patient's eye and provides the fundus oculi image information as an electronic image for later analysis.

The TRC-NW400 houses a color LCD monitor used for observation and display of a photographed image and a digital photography unit used for recording images. A photographed image may be recorded on a personal computer (hereinafter referred to as a PC), or on a commercially available storage device (such as a flash memory, a hard disk or a card reader/writer) connected to the TRC-NW400. A photographed image may also be printed on a commercially available digital printer connected to the TRC-NW400 or PC.

Patient information may be input on the control panel of the main unit or by using a commercially available data input device (for example: a bar code reader or a magnetic card reader) or PC.

Performance Data

The TRC-NW400 has been tested and found in compliance with the following recognized consensus standards:

IEC60601-1:2005 + CORR.1: 2006+CORR.2: 2007 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;

IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;

ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments;

ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection;

ISO 10940: 2009 Ophthalmic instruments - Fundus cameras

An analysis was performed of images captured with the TRC-NW400 and the predicate device which were formally evaluated and it was found that model eye images from the TRC-NW400 and from the predicate device were equivalent in terms of sharpness, image focus and resolution power. The results from the grading of clinical images from the TRC-NW400 were either equivalent or better than the predicate device. This study demonstrated that the TRC-NW400 is substantially equivalent to the predicate device.

Substantial Equivalence

The TRC-NW400 has the same intended use and similar indications, principles of operation, and technological characteristics as the TRC-NW300. The minor differences in the TRC-NW400's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the TRC-NW400 is as safe and effective

as the TRC-NW300. And also, the image grading result of color image shows that the TRC-NW400 is equivalent to the TRC-NW300 for color imaging. Thus, the TRC-NW400 is substantially equivalent to its predicate devices.